



Customer No. 22,852  
Attorney Docket No. 05394.0022

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Stewart COLE et al. )  
Application No.: 10/510,021 )  
Filed: October 1, 2004 ) Group Art Unit: 1645  
For: IDENTIFICATION OF VIRULENCE )  
ASSOCIATED REGIONS RD1 AND )  
RD5 LEADING TO IMPROVE )  
VACCINE OF M. BOVIS BCG AND M. )  
MICROTI )  
Examiner: Swartz, Rodney

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**RESPONSE TO RESTRICTION REQUIREMENT**

Applicant responds to the Office Action mailed April 25, 2007. A petition and fee for a one-month extension of time accompany this response.

In the Office Action mailed April 25, 2007 ("Office Action"), the Office required election under 35 U.S.C. §§ 121 and 372. According to the Office, the claims embody five distinct groups that are "not so linked to form a single general inventive concept under PCT Rule 13.1." Office Action, p. 2. The groups asserted by the Office are:

**Group I** Claims 1-26, 29, 43-49, and 57, drawn to transformed *M. bovis* BCG strain.

**Group II** Claims 1-23, 27, 28, 29, 43-49, and 57, drawn to transformed *M. microti* strain.

**Group III** Claims 30-42, 56, 58, and 59, drawn to DNA, cosmids, and plasmids.

**Group IV** Claims 50-53, drawn to DNA primers.

**Group V** Claims 54 and 55, drawn to antibodies.

The Office also requires an election of species. The Office stated that “[i]f Group I or II or III is elected, then a species election is to be done from the SEQ ID NO: 4 to SEQ ID NO: 28. If Group IV is elected, then a species election is to be done from the SEQ ID NO: 32, 33, 34, 35, 39, 40.” *Id.* at 3.

According to the Office, the DNA sequences of Groups I-IV “are well known in the art,” and “the only special technical feature appears to be the specifically transformed *M. bovis* or *M. microti*.” *Id.* The Office also asserts that the species “are not so linked to form a single general inventive concept under PCT Rule 13.1.” *Id.*

Applicants representative spoke with Examiner Swartz on July 11, 2007, via telephone. Examiner Swartz stated that SEQ ID NO: 1 should have been included in the groups.

Applicants provisionally elect Group 1, claims 1-26, 29, 43-49, and 57, with traverse. Applicants further provisionally elect species SEQ ID NO: 1.

**I. The Restriction Requirement Is Improper**

Applicants believe that the restriction requirement is improper. Restriction under PCT Rule 13.1 is improper where there is unity of invention. See M.P.E.P. § 1850. “Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.” *Id.* “Special technical features” are those “that define a contribution which each of the inventions, considered as a whole, makes over the prior art.” *Id.*

Unity of invention is present at least among Groups I and II, because these groups share SEQ ID NO:1, which is a special technical feature. Groups I and II comprise bacterial strains that have integrated all or part of the fragment named RD1-2F9 (SEQ ID NO: 1). The specification discloses that introduction of this sequence produced "profound phenotypic alteration." Specification, p. 4, lines 4. The Office has not alleged that the prior art teaches or suggests that bacterial strains, which have integrated all or part of the fragment named RD1-2F9 (SEQ ID NO: 1), exhibit such properties. Accordingly, at least Groups I and II exhibit unity of invention because they both comprise strains in which all or part of RD1-2F9 (SEQ ID NO: 1) is integrated.

Whether the transformed host is an *M. bovis* BCE strain or *M. microti* strain, a sequence search for SEQ ID NO: 1 should disclose both strains. Thus, there is no undue burden on the Office.

## **II. The Requirement of Species Election Is Improper**

Applicants also believe that the species election requirement is improper. SEQ ID NO: 1 contains SEQ ID NOs: 4-28. In other words, the sequences share the special technical feature of being part of SEQ ID NO:1. Moreover, a search of SEQ ID NO: 1 would identify SEQ ID NOs: 4-28.

## **III. Conclusion**

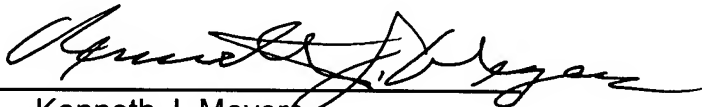
Applicants respectfully request that the Office withdraw the restriction requirement and search at least Groups I and II concurrently.

If there is any fee due in connection with the filing of this Reply, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: July 23, 2007

By: 

Kenneth J. Meyers  
Reg. No. 25,146  
Phone: 202-408-4033  
Fax: 202-408-4400  
Email: Ken.Meyers@Finnegan.com